1. Executive Summary of Procter & Gamble Recommendations to the Advanced Notice of Proposed Rulemaking

Stannous Fluoride

- *It is our recommendation that performance testing for SnF_2 dentifrices should consist of one test only; viz., the Plaque Glycolysis and Regrowth Model (PGRM) test. The clinical protocol, effectiveness criteria, and statistical methods are included in this document for the PGRM performance test.*
  [Ref. Section 2.D., pp. 27-35]

- *Procter & Gamble proposes that the monograph include an "antiplaque" statement of identity for stannous fluoride (SnF_2) and an unqualified "antiplaque" indication in addition to its "antigingivitis" statement of identity and qualified "antiplaque" indication. New clinical data demonstrating a significant effect on plaque mass reductions, in addition to previously reported significant reductions in plaque virulence and resultant pathogenicity, support this request.*
  [Ref. Section 3.A., pp. 43-63]

- *New in vitro microbiological data demonstrate that SnF_2 has broad spectrum bactericidal effects against plaque organisms associated with gingivitis. P&G proposes that these data warrant the inclusion of the same optional indication for SnF_2 as the Subcommittee recommended for essential oils, i.e. "helps (select one) 'control', 'inhibit', or 'kill' plaque bacteria that contribute to the development of (select one or more) 'gingivitis'; 'gingivitis, an early form of gum disease'; or 'bleeding gums'."* ***[Ref. Section 3.B., pp. 64-72]***

Cetylpyridinium Chloride (CPC)

- *P&G proposes that the final approved Performance Testing for Cetylpyridinium Chloride Rinses consists of the Disk Retention Assay (DRA) and the Plaque Glycolysis and Regrowth Model (PGRM). The testing protocol, effectiveness criteria, and statistical methods for the DRA and PGRM performance tests are included in this submission.* ***[Ref. Section 2.D. pp. 27-41]***

- *Effectiveness criteria for the Disk Retention Assay Performance Test for any 0.045% to 0.1% CPC-containing mouthrinse formulation is predicated on meeting or exceeding the CPC availability corresponding to the minimal threshold of clinical effectiveness recommended in the ANPR, i.e., ≥360ppm "available" CPC.*
  [Ref. Section 2.D. pp. 39-41]

- *New in vitro microbiological data show that CPC has broad spectrum bactericidal effects on plaque organisms associated with gingivitis. It is our position that these data warrant the inclusion of the same optional indication for CPC as the Subcommittee recommended for essential oils, i.e. "helps (select one) 'control', 'inhibit', or 'kill' plaque bacteria that contribute to the development of (select one or more) 'gingivitis'; 'gingivitis, an early form of gum disease'; or 'bleeding gums'."*
  [Ref. Section 4.A. pp. 73-81]

General Monograph Considerations and Wording

- *P&G continues to support the position that plaque claims should be considered cosmetic as long as they are qualified as cosmetic within the totality of the label. P&G believes legal and regulatory precedent support that the ultimate regulatory status (drug vs. cosmetic) is entirely predicated on intended use thereby permitting 'cosmetic' plaque claims separate and distinct from therapeutic plaque claims.*

Procter & Gamble is in full agreement with the Consumer Healthcare Products Association & Cosmetic Toiletry and Fragrance Association Task Group comments regarding cosmetic plaque claims. ***[Ref. Section 5.A. pp. 82-88]***

- *The monograph should allow for any alternate topical oral dose form in order to provide for maximum marketing flexibility of approved Category I antigingivitis and antigingivitis/antiplaque actives.* ***[Ref. Section 5.B. pp. 89-94]***

- *The indications sections should be revised so that the labeling is consistent for all products and broadened to allow multiple descriptions of drug action. The addition of a few words to the regulation for technical clarification will achieve this goal.* ***[Ref. Section 5.C. pp. 95-99]***

- *It is our position that the warnings specified in this rulemaking for all Category I active ingredients are inappropriate and are inconsistent with labeling for an NDA-approved gingivitis product. All products should include a statement regarding the need for regular dental checkups in the "Other information" section of the labeling. Antigingivitis products labeled for treatment or control of gingivitis should also include a warning to "Ask a dentist if the condition persists or worsens after regular use."* ***[Ref. Section 5.C.2. pp. 100-106]***

- *P&G believes that a section for Professional Labeling should be added to the monograph, i.e., site-specific therapy represents one of the conceivable professional uses for products regulated by this rulemaking.* ***[Ref. Section 5.D. pp. 107-108]***

- *It is P&G's position that clinical relevance of a 6-month gingivitis trial should be based on a statistically significant 15% reduction in gingivitis, which is the level of improvement achievable by consumers in a conscientiously applied home-based oral hygiene program.* ***[Ref. Section 5.E. pp. 109-119]***